

REMARKS

Claims 8-18 and 21-32 are pending. Claims 8, 11, 16-18 and 21-26 have been rejected and claims 9, 10 and 12-15 are withdrawn from consideration. No new matter has been added by way of the above amendments. For instance, claim 24 has been placed in independent format and the recitation of "crudely purified theanine and/or theanine extract" has been removed since these forms of theanine are generically encompassed by "purified theanine". Thus, this is a non-narrowing claim amendment that is not intended to exclude "crudely purified theanine" or "theanine extract". New claims 27 and 28 are supported by the present specification at page 5, line 18 and example 1. New claims 29 and 30 are supported by the present specification at page 5, line 20. Lastly, new claims 31 and 32 are supported by the present specification at page 23, specifically example 2. Accordingly, no new matter has been added.

In view of the following remarks Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Objection to the Claims

The Examiner has objected to claim 24 under 37 C.F.R. §1.75(c) asserting that it fails to further limit the claim upon which it depends. Applicants traverse and submit that claim 24

has been amended to render this objection moot. Reconsideration and withdrawal thereof are respectfully requested.

**Issues Under 35 U.S.C. §112, second paragraph**

The Examiner has rejected claim 24 under 35 U.S.C. §112, second paragraph asserting that the term "crudely" in claim 24 is a relative term and is therefore indefinite. Applicants traverse and submit that crude isolation of plant extracts is well known in the art and the Examiner's assertion that this is not probative is completely unsupported by evidence. However, in order to further prosecution Applicants have removed this term from the claim. Accordingly, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

**Issues Under 35 U.S.C. §102(b)**

The Examiner has rejected claim 24 under 35 U.S.C. §102(b) as being anticipated by "Applicants own admission". Applicants respectfully traverse this rejection.

The Examiner asserts that the instant claims are drawn to a method comprising administering to women with PMS a composition comprising theanine. Thus, the Examiner asserts that this method has inherently been practiced in this country since drinking tea is common and well known. Moreover, the Examiner asserts that people who drink tea are "reasonably expected" to include at least some of the women with PMS. Accordingly, the

Examiner asserts that claim 24 is inherently anticipated. Applicants assert that the Examiner's reasoning is flawed.

First, the Examiner has provided no evidence other than an unsupported assertion that people who drink tea are also reasonably expected to be women who suffer from PMS. Second, the Examiner's unstated assumption is that these people would hypothetically be drinking tea to treat the symptoms of PMS. These are baseless statements and assumptions which are in conflict with proven case law.

In relying upon the theory of inherency, an Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the alleged inherent characteristic "necessarily flows" from the teachings of the prior art. *Ex parte Levy*, 17 USPQ2d 1461 (BPAI 1990). However, the Examiner has simply stated, with no supporting evidence, that the people who drink tea are reasonably expected to include some women with PMS. This statement is far from supporting a determination that the alleged inherent characteristic "necessarily flows" from the teachings of the prior art. Accordingly, the Examiner has failed to present a *prima facie* case of anticipation. In fact, the Examiner's alleged case of inherent anticipation is legally flawed. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection.

Issues Under 35 U.S.C. §103(a)

The Examiner has rejected claims 8, 11, 16-18 and 21-26 under 35 U.S.C. §103(a) as being obvious over Fuji et al., JP 6100442 (hereinafter referred to as JP '442) in view of Merck Manual (15<sup>th</sup> Edition) and "Applicant". Applicants respectfully traverse this rejection.

The Examiner asserts that JP '442 teaches an anti-stress composition comprising L-theanine as the active ingredient. The Examiner admits that JP '442 fails to suggest or disclose employing its composition for the treatment of premenstrual syndrome. Regardless, the Examiner asserts that the Merck Manual can be used to satisfy this deficiency. However, a review of the Merck Manual simply reveals that PMS is a condition characterized by nervousness, irritability, emotion instability, depression and possible headaches, edema and mastalgia. The Examiner nonetheless reaches the unsupported conclusion that stress reduction is one of the known treatments of PMS in the art.

However, the Merck Manual simply states "counseling about the symptoms can increase self-understanding and lead to modification of activities for stress reduction." This statement does not support the Examiner's assertions. In fact, although stress may be related to PMS, the Examiner has not provided any evidence indicating that PMS may be suppressed or ameliorated by suppressing stress. The causes of PMS and the symptoms of PMS are very complicated. Accordingly, the statement in the Merck Manual that "counseling about the

symptoms can increase self-understanding and lead to modification of activities for stress reduction" has been incorrectly interpreted by the Examiner. Even today, it is not clear what causes PMS since various reports exist. Accordingly, Applicants submit that it is not known that any agents would suppress stress will also be effective in the treatment of PMS.

When the Examiner's rejection is viewed as a whole, it is completely unsupported by the cited art. Applicants are claiming a method of treating the individual in need of suppressing or meliorating a symptom accompanying diminished homeostasis, such as PMS. The Examiner has failed to present a valid *prima facie* case of obviousness against this rejection. Accordingly, Applicants respectfully request that this rejection be withdrawn. Reconsideration is requested.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No. 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition for an extension of two (2) months to December 2, 2002 in which to file a reply to the Office Action. The required fee of \$400.00 is enclosed herewith.

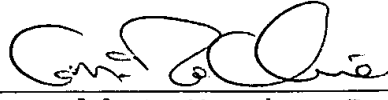
If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any


Appl. No. 09/655,336

additional fees required under 37 C.F.R. § 1.16 or under § 1.17;  
particularly, extension of time fees.

Respectfully submitted,

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Attachment: Version with Markings to Show Changes Made

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 24 has been amended as follows:

24. (Amended) [The method according to claim 23, whrein said isolated theanine is] A method for treating an individual in need of suppressing or ameliorating a symptom accompanying diminished homeosatsis, comprising:

administering a composition comprising purified theanine[, crudely purified theanine, and/or theanine extract] to the individual in need thereof.

New claims 27-32 were added.